

EXHIBIT H

Ralph Zipper, M.D.

1 IN THE COURT OF COMMON PLEAS
2 PHILADELPHIA COUNTY
3 TRIAL DIVISION
4 IN RE: PELVIC MESH LITIGATION MAY TERM 2013
5 No. 3913

6 PATRICIA L. HAMMONS,

7 Plaintiff,

8 vs.

9 ETHICON, INC., et al.,

10 Defendants,

11 - - -

12 SEPTEMBER 26, 2015

13 - - -

14 Deposition of RALPH ZIPPER, MD, held at Zipper
15 Urogynecology Associates, 200 South Harbor City
16 Boulevard, Suite 401, Melbourne, Florida, commencing
17 at 9:52 a.m., on the above date, before
18 Joan L. Pitt, Registered Merit Reporter, Certified
19 Realtime Reporter, and Florida Professional
20 Reporter.

21 - - -

22 GOLKOW TECHNOLOGIES, INC.
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24 deps@golkow.com

Ralph Zipper, M.D.

Page 10	Page 12
<p>1 a medical device.</p> <p>2 A. I'm providing consulting with regard to the</p> <p>3 design of medical devices, the methods required to use</p> <p>4 those devices. I'm providing consulting with regard to</p> <p>5 the labeling of those devices.</p> <p>6 I am providing consulting with regard to the</p> <p>7 development of the marketing and advertising materials,</p> <p>8 the print and advertising, the development of</p> <p>9 salesforce, salesforce training, professional education.</p> <p>10 Q. Do you have a written agreement with whatever</p> <p>11 these companies are?</p> <p>12 A. Still being negotiated. I'm working in good</p> <p>13 faith.</p> <p>14 Q. Does any of this consulting work have to do</p> <p>15 with treatment devices or medications for the treatment</p> <p>16 of either stress urinary incontinence or pelvic organ</p> <p>17 prolapse?</p> <p>18 MR. THORNBURGH: Objection.</p> <p>19 A. Yes.</p> <p>20 Q. Does any of the consulting work have to do with</p> <p>21 the use of mesh for the treatment of either stress</p> <p>22 urinary incontinence or pelvic organ prolapse?</p> <p>23 MR. THORNBURGH: Objection. Current consulting</p> <p>24 work?</p>	<p>1 Q. As a part of the consulting work that you're</p> <p>2 doing that we discussed briefly, are you currently</p> <p>3 involved in any clinical trial related to that treatment</p> <p>4 of pelvic organ prolapse for the companies for whom</p> <p>5 you're consulting?</p> <p>6 A. Can you please better define what you mean by</p> <p>7 "currently involved in"?</p> <p>8 Q. Are you designing a clinical trial?</p> <p>9 A. Yes.</p> <p>10 Q. Has the clinical trial started enrollment?</p> <p>11 A. No.</p> <p>12 Q. So about half an hour before we were supposed</p> <p>13 to start this deposition I received by e-mail on my</p> <p>14 iPhone an updated reliance list for you. Okay?</p> <p>15 I'm going to look at this and talk to you about</p> <p>16 it. I can't give it to you as an exhibit because I</p> <p>17 don't have it in a printed form.</p> <p>18 It indicates in the depositions section</p> <p>19 Dr. Lackey, Dr. Baker, and Dr. Rohrer, which I believe</p> <p>20 is the same as the reliance list that's part of</p> <p>21 Exhibit 1.</p> <p>22 Have you reviewed any other depositions to</p> <p>23 prepare to give opinions in this case other than those</p> <p>24 three?</p>
Page 11	Page 13
<p>1 MR. MORIARTY: Yeah, the current consulting</p> <p>2 work that we're talking about.</p> <p>3 A. The consulting work requires me to take into</p> <p>4 consideration the history of the mesh space, including</p> <p>5 everything from labeling, salesforce training, business</p> <p>6 modeling, and postmarket surveillance.</p> <p>7 Q. So it requires you to take all that into</p> <p>8 consideration, but are they mesh products?</p> <p>9 A. Can you please rephrase your question?</p> <p>10 Q. Sure. You said something about your consulting</p> <p>11 is taking into account the history of the mesh space,</p> <p>12 things of that nature.</p> <p>13 What I'm asking specifically is whether the</p> <p>14 device is a mesh product.</p> <p>15 MR. THORNBURGH: Objection.</p> <p>16 A. The device is not a mesh product.</p> <p>17 Q. Okay. I assume it's an alternative to a mesh</p> <p>18 product?</p> <p>19 A. A portion of my consulting work involves the</p> <p>20 development of a product and the commercialization of a</p> <p>21 product for the treatment of pelvic organ prolapse.</p> <p>22 Q. Is there anything else you need to add to the</p> <p>23 CV that you sent as part of Exhibit 1?</p> <p>24 A. Not that I'm aware of at this moment.</p>	<p>1 A. Yes. Actually, I had given that information</p> <p>2 earlier.</p> <p>3 Q. Tell me what other depositions you've read.</p> <p>4 A. I have -- it's not related to this case,</p> <p>5 because my entire experience and training, everything</p> <p>6 that happens to me in my life, is in consideration.</p> <p>7 MR. THORNBURGH: What case-specific depositions</p> <p>8 have you read in this case, is what he's asking.</p> <p>9 A. Oh, case-specific depositions. Just those</p> <p>10 three.</p> <p>11 Q. Okay. Then you have a literature list of</p> <p>12 about, by my count, and I did this a while ago, it was</p> <p>13 about 250 articles. Did you read all those?</p> <p>14 A. At some point in my career, yes.</p> <p>15 Q. And how was the list assembled?</p> <p>16 A. Key strokes.</p> <p>17 Q. What does that mean?</p> <p>18 A. It means I sat at a computer and I typed out</p> <p>19 the list. I reviewed the literature, which I do on a</p> <p>20 weekly basis, or at this time of year, on a daily basis.</p> <p>21 Also, from time to time I might be reading the</p> <p>22 expert opinion of defense counsel and looking at their</p> <p>23 reliance list and realize that there are 10 or 15 great</p> <p>24 articles on there that I have read in the past I am</p>

Ralph Zipper, M.D.

Page 14	Page 16
<p>1 relying on.</p> <p>2 When you've been doing this for as long as I</p> <p>3 have, you've read thousands and thousands of articles,</p> <p>4 and it's difficult to remember the thousands and</p> <p>5 thousands of articles that have led to the development</p> <p>6 of your opinion over the years.</p> <p>7 And the ones that are more current and fresher</p> <p>8 in the mind quickly get added to the reliance list, but</p> <p>9 the reliance list continually grows; A, because I'll</p> <p>10 spontaneously remember articles that I've read that are</p> <p>11 meaningful and relevant to this case; or because I'll be</p> <p>12 reminded of them by defense experts who are relying on</p> <p>13 articles that I've read and they're meaningful and</p> <p>14 relevant in this case.</p> <p>15 Q. Okay. Just so we're clear, the original</p> <p>16 reliance list is not necessarily articles that you read</p> <p>17 just for this case, it's a collective and cumulative</p> <p>18 experience for you; is that correct?</p> <p>19 MR. THORNBURGH: Objection.</p> <p>20 A. That's correct.</p> <p>21 Q. Okay. New on the reliance list are the reports</p> <p>22 of Dr. Weber, Julie Drolet, and Joyce Lowman. I assume</p> <p>23 you read all those three?</p> <p>24 A. Yes, I have.</p>	<p>1 the time you received her report and today?</p> <p>2 A. Not only did I read many of the articles in the</p> <p>3 Dr. Drolet, Lowman, and Weber reports, but the reading</p> <p>4 of those articles was not a first reading of those</p> <p>5 articles. The reliance list of those experts caused me</p> <p>6 to recollect those articles and go back and look at them</p> <p>7 again.</p> <p>8 MR. MORIARTY: Okay. What I'd like to do, with</p> <p>9 Dan and Kila's permission, is when we get a chance</p> <p>10 today, tomorrow, this week, print this from Kila's</p> <p>11 e-mail, or your assistant's e-mail, and just reserve</p> <p>12 an exhibit for it. Is that acceptable?</p> <p>13 MR. THORNBURGH: Yeah, that's fine.</p> <p>14 MR. MORIARTY: Okay.</p> <p>15 MS. SUTHERLAND: Nobody has it already printed,</p> <p>16 do you want to ask that?</p> <p>17 MR. MORIARTY: You didn't print it, did you?</p> <p>18 MR. THORNBURGH: I don't have it printed, so I</p> <p>19 don't think we have any extras, no, but we'll get it</p> <p>20 for you probably today.</p> <p>21 MR. MORIARTY: It's 41 pages long, so we can</p> <p>22 wait until the weekday.</p> <p>23 BY MR. MORIARTY:</p> <p>24 Q. Now, Doctor, after reviewing the reliance list,</p>
Page 15	Page 17
<p>1 Q. And then you added to the reliance list</p> <p>2 citations from the report of Anne Weber, did you not?</p> <p>3 A. Yes, I did.</p> <p>4 Q. And it looks like some of those are company</p> <p>5 documents; correct?</p> <p>6 A. This is correct.</p> <p>7 Q. Then medical literature from the report of</p> <p>8 Julie Drolet, and there is a long list, which I've not</p> <p>9 had an opportunity to count, but you did add some things</p> <p>10 from Dr. Drolet's literature list; correct?</p> <p>11 A. As I referenced a few moments ago,</p> <p>12 Mr. Moriarty, when I read through the opinions of</p> <p>13 defense counsel's experts, it often causes me to realize</p> <p>14 that those are articles that I have read in the past</p> <p>15 that I have considered in my opinion, and they have been</p> <p>16 added to my reliance list.</p> <p>17 Q. Okay. Do you know how many of these you</p> <p>18 specifically read between the time you got Dr. Drolet's</p> <p>19 report and today?</p> <p>20 A. Many.</p> <p>21 Q. And then you did the same thing for the</p> <p>22 literature list of Dr. Lowman; is that correct?</p> <p>23 A. This is correct.</p> <p>24 Q. And did you read some of these articles between</p>	<p>1 you drafted a report that is part of Exhibit 1; is that</p> <p>2 correct?</p> <p>3 MR. THORNBURGH: Objection.</p> <p>4 Q. I'm sorry. After reading whatever you felt was</p> <p>5 appropriate to prepare for opinions in this case, you</p> <p>6 drafted the report that's Exhibit 1; correct?</p> <p>7 A. The report that is Exhibit 1 is based on my</p> <p>8 review of the medical records of Mrs. Hammons, my</p> <p>9 knowledge, training, and experience over the last 20</p> <p>10 some years, which includes my extensive reading of the</p> <p>11 medical literature, and my reliance list.</p> <p>12 Q. And then at some point later you drafted this</p> <p>13 supplemental report dated September 17, 2015; correct?</p> <p>14 A. That's correct.</p> <p>15 (Zipper Exhibit No. 7 was marked for</p> <p>16 identification.)</p> <p>17 BY MR. MORIARTY:</p> <p>18 Q. And this is just a one-paragraph letter talking</p> <p>19 about the medical bills from Dr. Lackey and Dr. Heit</p> <p>20 being reasonably -- reasonable and medically necessary;</p> <p>21 correct?</p> <p>22 A. This is correct.</p> <p>23 Q. Is there any place in your Exhibit 1, your</p> <p>24 report, in which you gave an opinion that Mrs. Hanson's</p>

Ralph Zipper, M.D.

<p style="text-align: right;">Page 102</p> <p>1 I do not consider it appropriate to really assess this</p> <p>2 dyspareunia until the healing process is substantially</p> <p>3 completed itself.</p> <p>4 So I would expect anybody to have sensitivity</p> <p>5 over an incision, whether it be on their abdomen, their</p> <p>6 knee, or their elbow, or their vagina, in the first</p> <p>7 several months following surgery. But given time for</p> <p>8 appropriate healing, my guesstimate on my native</p> <p>9 tissue-related dyspareunia rate is in the 2 to 4 percent</p> <p>10 range.</p> <p>11 Q. Okay. Now, originally on your reliance list</p> <p>12 there were no Ethicon company documents. Your updated</p> <p>13 reliance list has some. Do you know when you reviewed,</p> <p>14 received and reviewed, those documents?</p> <p>15 A. No, I do not. I couldn't tell you which.</p> <p>16 There were perhaps one or two that are more recent, but</p> <p>17 I could not tell you when I first reviewed them.</p> <p>18 However, having looked at the opinions of the</p> <p>19 other experts, it caused me to dig a little bit into the</p> <p>20 Corvela database, and upon digging a little bit into the</p> <p>21 Corvela database, I found additional information that I</p> <p>22 considered important and relevant to my case-specific</p> <p>23 opinion.</p> <p>24 Q. Okay. Of the patients in whom you performed</p>	<p style="text-align: right;">Page 104</p> <p>1 rare occasion, if someone expressed interest in my data,</p> <p>2 other than that, I've not endeavored to publish.</p> <p>3 Q. How many times do you believe you used Prolift,</p> <p>4 either anterior, posterior, or total?</p> <p>5 A. I can say with rather vivid memory and a high</p> <p>6 agree of confidence that my use of Prolift was limited</p> <p>7 and short-lived secondary to my dissatisfaction with the</p> <p>8 product.</p> <p>9 Q. Can you tell me when you used it?</p> <p>10 A. No. Shortly after it came to market.</p> <p>11 Q. How many patients do you think you implanted</p> <p>12 with Prolift?</p> <p>13 A. My guesstimation is, and, once again, this is a</p> <p>14 guesstimation, but my frustration with the design of the</p> <p>15 product and the defective nature of the product caused</p> <p>16 me to discontinue use of the product certainly after</p> <p>17 less than 10 uses, although I have explanted most likely</p> <p>18 over 100 pieces of Prolift for complications such as</p> <p>19 pain, erosion, and dyspareunia.</p> <p>20 Q. I'm sorry. What was that number?</p> <p>21 A. Over 100 pieces of Prolift explanted for</p> <p>22 complications such as pain, erosion, and dyspareunia.</p> <p>23 Q. How many explants do you believe you have done</p> <p>24 overall for mesh used for pelvic organ prolapse repair?</p>
<p style="text-align: right;">Page 103</p> <p>1 transvaginal mesh repairs for pelvic organ prolapse, do</p> <p>2 you have any estimate from the number of those patients</p> <p>3 who have suffered clinical signs and symptoms of</p> <p>4 contraction?</p> <p>5 MR. THORNBURGH: Objection. Asked and</p> <p>6 answered.</p> <p>7 MR. MORIARTY: No, I asked about erosion and</p> <p>8 dyspareunia. I haven't asked about contraction.</p> <p>9 MR. THORNBURGH: I think they're interrelated.</p> <p>10 A. My findings are, for clinical signs and</p> <p>11 symptoms for contraction, approximately 15 percent for</p> <p>12 self-tailored mesh and approximately 90 percent for</p> <p>13 armed mesh, which I believe is consistent with the</p> <p>14 findings of Velemir, who evaluated contraction with</p> <p>15 Prolift.</p> <p>16 Q. Now, I've asked you about your experience with</p> <p>17 all these different procedures and complications and</p> <p>18 whatnot. Other than the poster presentation that I</p> <p>19 marked and that we discussed earlier, have you published</p> <p>20 the results of your experience with these procedures in</p> <p>21 any peer-reviewed medical literature?</p> <p>22 A. No. I consider myself more of a clinician and</p> <p>23 my life and my career has been dedicated to the</p> <p>24 treatment of patients and not to the publication. On</p>	<p style="text-align: right;">Page 105</p> <p>1 A. Hundreds, including Prolift last week.</p> <p>2 Q. So you've explanted hundreds of transvaginal</p> <p>3 meshes used for pelvic organ prolapse repair and some</p> <p>4 subset of that has been Prolift?</p> <p>5 A. I've explanted hundreds of pieces of Prolift</p> <p>6 mesh for both erosion, severe chronic pain, and</p> <p>7 dyspareunia.</p> <p>8 Q. Now, when you say "explanted" and you mentioned</p> <p>9 "erosion," are you talking about --</p> <p>10 A. Symptomatic erosions.</p> <p>11 Q. Are you talking about just a small -- the small</p> <p>12 eroded area or a wider explant of the mesh?</p> <p>13 A. I do what I feel is necessary to treat the</p> <p>14 patient based on their symptoms and physical findings.</p> <p>15 Typically it's a wider explantation.</p> <p>16 The patient I -- Prolift patient I treated just</p> <p>17 last week had been suffering with severe, debilitating,</p> <p>18 chronic pelvic pain, had failed multiple surgeries</p> <p>19 elsewhere. Nobody was able to help her. And I did a</p> <p>20 very large wide dissection and was able to remove her</p> <p>21 proximal Prolift arms down to the level of the</p> <p>22 sacrospinous ligament, and she -- after years and years</p> <p>23 of suffering and pain, she's achieved 25 to 50 percent</p> <p>24 improvement.</p>